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In the

Supreme Court of the United States

October Term, 1995

LORA LOHR AND MICHAEL LOHR,
Cross-Petitioners,

v.

MEDTRONIC, INC.
Cross-Respondent.

On Cross-Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

REPLY BRIEF IN SUPPORT OF CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI

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In an understandable desire to preserve the portions of the Eleventh Circuit's preemption ruling favorable to it, cross-respondent Medtronic, Inc. reads the various circuit court decisions on the scope of preemption under the Medical Device Amendments ("MDA") to find harmony, or at least potential harmony, where deep conflicts exist. It does so while admitting that there is an irreconcilable conflict on a key issue on which both the petition and cross-petition seek review—whether the MDA preempts state-law damage claims at all. And in urging the Court to deny the cross-petition, Medtronics overlooks the central lessons of *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), namely that (1) if there is preemption at all, preemption defenses must be decided on a claim-by-claim basis, and (2) it is sensible for

the Court to look at a range of claims when considering the scope of preemption under a particular federal statute, as granting the petition and cross-petition would enable the Court to do. *See also American Airlines, Inc. v. Wolens*, 115 S. Ct. 817 (1995). For the following reasons, review of the cross-petition should be granted along with the corresponding petition in No. 95-754.

ARGUMENT

First, cross-respondent does not, and cannot, harmonize the Ninth Circuit's decision in *Kennedy v. Collagen Corp.*, 67 F.3d 1453 (1995), which held that the MDA does not preempt any damage claims, with the decision below, which held that the MDA does preempt some damage claims. *See* Pet. App. 11a. Cross-respondent argues that review of the cross-petition would be inappropriate because rehearing en banc might be granted in *Kennedy*. However, that appears unlikely since the principal purpose of en banc review is to reconcile *intra*-circuit conflicts, *see* Fed. R. App. P. 35(a)(1), and *Kennedy* is the Ninth Circuit's only preemption case involving a Class III medical device.[1]

Cross-respondent also argues that, even if the Ninth Circuit denies rehearing en banc in *Kennedy*, review should be denied on the cross-petition because the petition in No. 95-754 also "squarely presents the question whether the FDCA preempts common law claims." Opp. 8. While true,

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[1] Cross-respondent claims that *Kennedy* is inconsistent with dicta in another Ninth Circuit case, *Anguiano v. E.I. du Pont de Nemours & Co.*, 44 F.3d 806 (1995), *see* Opp. 8, but does not mention that *Anguiano* concerned a Class II medical device and held that there was *no* preemption under the circumstances presented there.

that point only underscores the wisdom of granting the cross-petition. Once it is conceded that both the petition and the cross-petition present the same fundamental question of whether the MDA preempts damage claims at all, there is no reason not to grant both petitions. This is especially true here, since granting review of only the petition might bar cross-petitioners from pursuing their failure-to-warn and manufacturing-defect claims even if this Court holds that no damage claims are preempted by the MDA.

Second, the Eleventh Circuit held that cross-petitioners' failure-to-warn and manufacturing-defect claims were preempted even if those common-law claims were based on duties identical to federal requirements. Pet. App. 13a-14a. The court of appeals so ruled even though 21 U.S.C. § 360k(a) preempts only state and local requirements that are "different from, or in addition to" federal requirements. Cross-respondent calls the Eleventh Circuit's ruling on this issue "dicta" because the court did not decide whether such a claim would be valid under Florida law. Opp. 9-10 & n.4. But the court of appeals' ruling plainly is not dicta because it was applied to the cross-petitioners who, as a result, are barred from litigating their failure-to-warn and manufacturing-defect claims based on Medtronic's violation of federally imposed duties.

Cross-respondent also claims that this ruling is "dicta" because the Eleventh Circuit reached the issue even though it was not raised in the opening brief below. Opp. 10-11. But having been raised and decided by the court of appeals, the issue is properly presented for review before this Court. *See* R. Stern, *et al.*, *Supreme Court Practice* § 6.26, p. 344 (7th ed. 1993).

Even less relevant to the question whether review should be granted is cross-respondent's claim that cross-

petitioners' district court complaint does not raise this issue. Opp. 9. The question is not whether the complaint specifically cites federal regulatory requirements, but whether, as the court of appeals noted (Pet. App. 13a n.8), the complaint is broad enough to encompass claims for failure to abide by federal warning and manufacturing requirements. Under the federal "notice" pleading regime, cross-petitioners' allegations that cross-respondent failed to conform to negligence and strict liability standards regarding its duties to warn and to manufacture its products without defect plainly encompass such claims. *See* Complaint, ¶¶ 6, 11, R.E. 8, 9; *accord National Bank of Commerce v. Kimberly-Clark Corp.*, 38 F.3d 988, 992 n.2 (8th Cir. 1994). This is particularly true here, where cross-respondent's motion for summary judgment on preemption grounds was filed early in the case before substantial discovery had taken place.

As for the conflicts with other courts of appeals on this question, cross-respondent misreads the relevant cases. Despite cross-respondent's protestations to the contrary, both the lead and concurring opinions in *National Bank of Commerce*, 38 F.3d at 993, *id.* at 998 (Loken & Fagg, J.J., concurring), are clear that there is no preemption under the MDA where a state-law claim would reach no further than the federal requirement.

Further, cross-respondent quotes out of context a statement in *Michael v. Shiley*, 46 F.3d 1316, 1329 (3d Cir.), *cert. denied*, 116 S. Ct. 67 (1995), in which the Third Circuit held that a claim premised on *fraud* on the Food and Drug Administration ("FDA") was preempted because it was up to the agency to police its own "procedures" for premarket approval. But as to the question presented here, *Michael* states, without equivocation, that there is no

preemption where "it is the FDA's own [substantive] requirement that [plaintiff] would have the state enforce." *Id.* at 1328.

Finally, quite apart from *National Bank of Commerce* and *Michael*, cross-respondent simply ignores the Seventh Circuit's recent decision in *Mitchell v. Collagen Corp.*, 67 F.3d 1268, 1281-82 (7th Cir. 1995), and other lower court rulings, *see* Cross-Petition 15 n.8, which would permit claims alleging violations of federal standards to go forward. In sum, on this issue, as with many other issues of MDA preemption, the circuits are in disarray and review by this Court is necessary.

Finally, cross-respondent all but ignores the division among the federal courts on the proper interpretation of 21 C.F.R. § 808.1(d), which demands the existence of "specific counterpart [federal] requirements applicable to a particular device" to trigger preemption of a state or local requirement. This is important because, despite the language of § 808.1(d), the court of appeals preempted cross-petitioners' failure-to-warn and manufacturing-defect claims on the basis of federal labelling and manufacturing practices rules applicable to medical devices *generally*. Pet. App. 29a-32a. The Eleventh Circuit explicitly acknowledged, however, that its view was in conflict with those of several courts, including the Ninth Circuit. Pet. App. 20a-21a & n.15. The Ninth Circuit decision referred to by the court of appeals was *Anguiano*, 44 F.3d at 809-10, not *Kennedy*, which, building on *Anguiano*, held that 21 C.F.R. § 808.1(d) demonstrates that damage claims are not preempted at all. 67 F.3d at 1456-57. Because this conflict involves the regulations of the agency charged by Congress with administering and

interpreting the MDA, review of this issue is particularly important.[2]

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[2] This issue includes the general question of deference to the FDA's MDA preemption regulations. Although we do not concur with the Eleventh Circuit's reading of 21 C.F.R. § 808.1(d), the court of appeals properly deferred, under *Chevron U.S.A., Inc. v. National Resource Defense Council, Inc.*, 467 U.S. 387, 842-45 (1984), to what it believed to be the agency's views. *See* Pet. App. 17a. On the other hand, at least one court of appeals has indicated that the FDA's preemption regulations are not proper interpretations of the MDA and, thus, are not entitled to deference. *King v. Collagen Corp.*, 983 F.2d 1130, 1139 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993).

CONCLUSION

As stated in their response to the petition in No. 95-754, the petition in that case should be granted. For much the same reasons—to resolve the deepening conflicts among the circuits and in the state courts—the cross-petition for a writ of certiorari should be granted as well.

Respectfully submitted,

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